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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,835	RICHARDSON ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 21, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *4,14,18-23 and 27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-12, 14-17 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/1/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-3, 5-12, 14-17 and 24-26 in the reply filed on June 21, 2004 is acknowledged. The traversal is on the ground(s) that all inventions are embodiments of a single generic invention. The basis for this argument is the existence of a single independent claim from which all other claims depend. This is not found persuasive, in part because applicant's assertion is factually incorrect. There are two independent claims in the instant application, claim 1 and claim 18. Whether claims are written in independent or dependent form is solely the choice of the applicant and the number of independent claims is irrelevant to whether an invention is restrictable.

2. The applicant asserts that all claims are drawn to a single inventive concept, that is, the elimination of reduction of normal but undesired tissue via injection of a controlled release formula and that the different groups are simply different embodiments which are at best species. This is not the case. Not only are there in fact independent and distinct methods as evidenced by the two methods recited in claims 1 and 18, but also the use of different substances in the controlled release formula is a basis for restriction. The requirement for holding inventions to be unrelated is that they must have different functions, different effects or different modes of operation. Three-way distinctness is not required, two inventions can perform the same function and produce the same effect but if each does it by a different mechanism, the inventions are restrictable. The

disclosed inventions have different modes of operations. A peptide, a small molecule and a nucleic acid operate by different mechanisms within a cell or an organism.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claim 3 is objected to because of the following informalities: there are multiple periods at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-12, 14-17 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is drawn to a method of eliminating or reducing normal but undesired tissue in a patient by injection of a controlled release formulation at a local area containing the undesired tissue. The use of the phrase "local area" is indefinite. It is unknown what constitutes a local area; whether "local area" encompasses a certain physical distance, a certain depth of injection or the underside of a limb that contains undesired tissue on the upper side of the limb.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-12, 14 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

5. This is a written description rejection. Claim 1 is drawn to a method of eliminating or reducing normal but undesired tissue in a patient by injection of a controlled release formulation comprising a substance which eliminates or prevents formation of cells of the undesired tissue at a local area containing the undesired tissue. The claimed method encompasses a broad genus of tissue types and a broad genus of compounds disclosed as being capable of reducing or eliminating normal but undesired tissue.

6. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

7. The claimed method encompasses a broad genus of tissue types. The specification discloses that the claimed method is useful for reduction or elimination of

fat tissue, pathologic hyperplasia, benign tumor, neointimal thickened vasculature, mole, hair and bone tissue. However, the claims are not limiting; other types of tissue not disclosed in the specification are encompassed by the claimed invention. The specification does not provide adequate guidance of how to reduce or eliminate all types of tissue encompassed by the instant invention. No guidance is provided as to what active substances would reduce or eliminate all types of tissues nor is there any guidance that would lead the skilled artisan to envision what structure these active substances would have. The examples provided in the specification describing the elimination of fat tissue are not sufficient to describe the entire genus of types of tissues that are encompassed by the claimed method.

8. The claimed method also encompasses a broad genus of types of compounds useful as the substance that reduces or eliminates the tissue. The specification discloses that classes of active compounds include proteins, including peptides that are fragments of larger proteins, small molecule drugs and nucleic acids in the form of DNA in expression vectors or anti-sense RNA. The examples in the specification describe a single substance, TNF-α, to eliminate fat tissue and the prior art describes the use of another protein, OB protein, also known as leptin, to eliminate fat tissue. The examples provided in the instant invention and in the prior art of reducing or eliminating fat tissue with two different proteins are not sufficient to adequately describe even the sub-genus of protein active compounds to reduce or eliminate fat tissue, much less the other categories of active compounds such as nucleic acids and small molecule drugs that are disclosed as able to reduce or eliminate fat tissue. The examples given using

proteins as the active substance to reduce or eliminate fat tissue provide no guidance as to the structure of proteins that would reduce or eliminate any of the other types of tissues encompassed by the instant invention nor do they provide guidance as to the structure of nucleic acids or small molecules that would reduce or eliminate fat tissue or any other type of tissue encompassed by the claimed method. From the description given in the specification, the skilled artisan cannot envision the full genus of compounds that would reduce or eliminate all the types of normal but undesired tissue encompassed by the instant invention.

9. *Vas-Cath Inc, v. Mahurkar*, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description inquiry, *whatever is now claimed*. (See page 1117.) The specification does not "clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116) As discussed above the skilled artisan cannot envision the structure of the encompassed genus of types of active substances that can reduce or eliminate the types of tissues claimed. Adequate written description requires more than a mere statement that is part of the invention and reference to a method of isolating it.

10. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 20 USPQ2s 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

11. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 5, 6, 9-12, 14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg et al. (WO98/46211, October 22, 1998).

13. Claim 1 is drawn to a method of eliminating or reducing undesired tissue by injection of a controlled release formula containing a substance that eliminates or prevents formation of the cells of the undesired tissue. Claim 2 depends from and further limits claim 1 by stating the undesired tissue is fat. Claim 3 depends from and further limits claim 1 by stating the substance is TNF-α. Claims 5, 6 and 14 depend from and further limit claims 1, 2 and 3, respectively, by stating the controlled release carrier is comprised of poly (lactide-co-glycolide) material. Claims 9 and 10 depend from and further limit claims 1 and 2, respectively, by stating that the active substance in the controlled release formula is released over the course of at least 3 days. Claims 11 and 12 depend from and further limit claims 9 and 10, respectively, by stating that the active substance is released in a substantially equal amount over each day of release.

Claim 17 depends from and further limits claim 1 by stating that the controlled release carrier is chosen from a list of polymers, including alginates or modified alginates.

14. Goldenberg et al. disclose sustained release formulations using alginates as carriers. They further disclose that the active substance can include anti-obesity factors and can be TNF-α (see page 11, lines 3-27). The formulations can also contain copolymers of lactic and glycolic acid (see page 13, lines 31-33). The formulations are administered by subcutaneous injection. Examples given in the reference describe administration of a formulation by subcutaneous injection in the neck of rats, who lost body weight after administration. Pharmacokinetic studies show the active substance is released at a constant rate for at least 112 hours (example 3, page 24). Since a subcutaneous injection in this area of a mouse would necessarily involve injection into fat tissue and since weight loss indicates reduction or elimination of fat tissue, Goldenberg et al. disclose the method of claim 1 and all the limitations of claims 2-3, 5, 6, 9-12, 14 and 17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-3, 5-12, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. as applied to claims 1-3, 5, 6, 9-12, 14 and 17 above. Claims 7 and 8 depend from and further limit claims 1 and 2, respectively, by stating the controlled release formula is injected multiple times in the local area of the tissue being reduced. Goldenberg et al. teach the use of TNF-α in a controlled release formulation to reduce weight and thereby reduce or eliminate fat and further teach that the use of controlled release formulations can reduce the frequency of injections necessary to achieve the desired effect. Goldenberg et al. teach in their examples use of a single injection into rats for the purpose of performing pharmacokinetic studies. They do not teach the delivery of the controlled release formula by the use of multiple injections.

16. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Goldenberg et al. to reduce fat tissue using a controlled release formulation by delivering the controlled release formulation in multiple injections. A person of ordinary skill in the art would have been motivated to do so because Goldenberg et al. contemplate multiple injections and although the

disclosed examples use a single injection for the purposes of pharmacokinetic studies, the person of ordinary skill in the art would recognize the need for longer term treatment and would recognize that multiple injections would meet this need. A person of ordinary skill in the art would have had a reasonable expectation of success in modifying the method of Goldenberg et al. by recognizing that determination of the number of injections needed to accomplish reduction or elimination of tissue would be an obvious extension of the examples given by Goldenberg et al. because it is merely an optimization of the disclosed methods.

17. Therefore, the invention of claims 1-3, 5-12, 14 and 17 would have been obvious, as a whole, at the time the instant invention was made.

18. Claims 1-3, 5, 6, 9-12 and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. as applied to claims 1-3, 5, 6, 9-12, 14 and 17 above, and further in view of Hutchinson et al. (Biodegradable polymers for the sustained release of peptides, *Biochemical Society Transactions* 1985, vol 13, pages 520-523), Ogawa et al. (*In Vivo* Release Profiles of Leuprolide Acetate from Microcapsules Prepared with Polylactic Acids or Copoly(Lactic/Glycolic) Acids and *in Vivo* Degradation of These Polymers, *Chemical Pharmaceutical Bulletin*, 1988, vol 36, pages 2576-2581) or Johnson et al. (A month-long effect from a single injection of microencapsulated human growth hormone, *Nature Medicine*, 1996, vol 2, pages 795-799).

19. Claims 1-3, 5, 6, 9-12, 14 and 17 are described in the previous 102 rejection. Claims 15 and 16 each depend from and further limit claim 14. Claim 15 states that

TNF-α is loaded into the controlled release carrier in an amount of .1 to 20% by weight. Claim 16 states that the *in vivo* release of the TNF-α occurs for a period of 7-60 days. Goldenberg et al. teach the use of TNF-α in a controlled release formulation to reduce weight and thereby reduce or eliminate fat. They do not teach the specific loading nor the duration of release recited in claims 15 and 16.

20. Hutchinson et al. teach the use of Zoladex in poly (lactide-co-glycolide) microspheres. The peptide is loaded in an amount of 3-20% by weight and *in vivo* release is followed for a period up to 50 days (see figure 2 and description on page 522).

21. Ogawa et al. teach the use of leuprolide acetate in poly (lactide-co-glycolide) microspheres. The peptide is loaded in an amount of 10% by weight (see page 2577, "Preparation of Microcapsules and Plates) and the *in vivo* release is followed for a period of 35 days (see page 2581, table III).

22. Johnson et al. teach the use of recombinant human growth hormone in poly (lactide-co-glycolide) microspheres. The peptide is loaded in an amount of 15% (see page 795, last sentence) and *in vivo* release is followed for more than 60 days (see p 796-797 and figure 2).

23. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to perform the method of Goldenberg et al. to reduce or eliminate fat tissue using a controlled release formulation with the amount of drug loaded in the microspheres and for the periods of time taught by each of Hutchinson et al., Ogawa et al. and Johnson et al. A person of ordinary skill in the art would have been motivated to

do so because Hutchinson et al., Ogawa et al. and Johnson et al. each teach the use of poly (lactide-co-glycolide) microspheres with a similar amount of drug loaded on the microspheres and a similar duration of release, indicating that such loadings and release durations are a routine characteristic of such controlled release formulations. A person of ordinary skill in the art would have had a reasonable expectation of success in using the method taught by Goldenberg et al. to reduce fat tissue using controlled release formulations with the amount of drug loaded in the microspheres and for the periods of time taught by each of Hutchinson et al., Ogawa et al. and Johnson et al. because Goldenberg et al. taught their method to reduce fat tissue using a controlled release formulation using techniques well known in the art and demonstrate this method actually successfully reduces fat tissue and Hutchinson et al., Ogawa et al. and Johnson et al. each teach the use of poly (lactide-co-glycolide) microspheres with a similar amount of drug loaded on the microspheres and a similar duration of release, indicating that such loadings and release durations are a routine characteristic of such controlled release formulations.

24. Therefore, the invention of claims 1-3, 5, 6, 9-12 and 14-17 would have been obvious, as a whole, at the time the instant invention was made.

25. Claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. as applied to claims 1-3, 5, 6, 9-12, 14 and 17 above, and further in view of Silvestri et al. (US 5,126,147, June 30, 1992). Claims 1-3, 5, 6, 9-12, 14 and 17 are described in the previous 102 rejection. Claim 24 depends from and further limits claim 1 by stating that the controlled release formulation

comprises two or more active substances. Claim 25 depends from and further limits claim 24 by stating the two active substances are released at different times.

26. Goldenberg et al. teach the use of TNF-α in a controlled release formulation to reduce weight and thereby reduce or eliminate fat. They do not teach that such formulations can contain more than one active substance that can be released at different times.

27. Silvestri et al. teach controlled release formulations that are multiphasic, releasing the active ingredient at different rates at different times (see col 3, line 64-col 4, line 56). They teach that the multiphasic formulations can contain two or more active substances and that TNF-α can be the active substance (see col 1, lines 54-68). They also teach that their formulations can be composed of poly(lactide)/poly(glycolide) copolymers, poly(orthoesters) and polyanhydrides (see col 2, lines 15-23).

28. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to perform the method of Goldenberg et al. to reduce or eliminate fat tissue using a controlled release formulation with the controlled release formulations of Silvestri et al. A person of ordinary skill in the art would have been motivated to do so because the controlled release formulations of Silvestri et al would be a desirable improvement of the method of Goldenberg et al., because Silvestri et al. teaches controlled release formulations that are multiphasic, allowing release of an active substance at different rates at different times or allowing the use of multiple active substances. A person of ordinary skill in the art would have had a reasonable expectation of success in using the method taught by Goldenberg et al. to reduce or

eliminate fat tissue using controlled release formulations because Goldenberg et al. taught their method to reduce or eliminate fat tissue using a controlled release formulation using techniques well known in the art and demonstrate this method actually successfully reduces fat tissue and Silvestri et al. teach a type of controlled release formulation with improved properties and teach that it could be used in a method similar to that of Goldenberg et al. with a reasonable expectation of the same results.

29. Therefore, the invention of claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 would have been obvious, as a whole, at the time the instant invention was made.

30. Claims 1-3, 5, 6, 9-12, 14, 17 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg et al. and Silvestri et al. as applied to claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 above, and further in view of Merwin et al. (Acidic Fibroblast Growth Factor-Pseudomonas Exotoxin Chimeric Protein Elicits Antiangiogenic Effects on Endothelial Cells, *Cancer Research*, 1992, vol. 52, p 4995). Claims 1-3, 5, 6, 9-12, 14, 17, 24 and 25 are described in the previous 103 rejection. Claim 26 depends from and further limits claim 25 by stating that the two active substances are an anti-angiogenic compound and a substance that induces apoptosis. Goldenberg et al. and Silvestri et al. teach the use of controlled release formulas containing TNF-α, an inducer of apoptosis, and also teach that the controlled release formula can contain another active substance. They do not teach the use of an anti-angiogenic compound as the other active substance.

31. Merwin et al. teach that a chimeric protein containing acidic fibroblast growth factor (hereafter aFGF) exhibits antiangiogenic effects, inhibiting protein synthesis in

epithelial cells and preventing the formation of tubular structures in 3D culture, a model for angiogenic response. (see section entitled "Antiangiogenic response to aFGF-PE, page 4997 and 4999)

32. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to perform the method of Goldenberg et al. to reduce or eliminate fat tissue using a controlled release formulation with the controlled release formulations of Silvestri et al and to use an antiangiogenic compound as the other active substance suggested by Silvestri et al. A person of ordinary skill in the art would have been motivated to do so because the addition of a second active substance was suggested by Silvestri et al. and Merwin et al. teach that aFGF chimeric protein prevents angiogenesis in rat epithelial cells removed from the epididymal fat pad. Since the *in vitro* studies were conducted on cells derived from the fat pad of a rat, it would be expected that reducing angiogenesis in such cells would lead to reduction in fat tissue. A person of ordinary skill in the art would have had a reasonable expectation of success in using the method taught by Goldenberg et al. to reduce or eliminate fat tissue using controlled release formulations because Goldenberg et al. taught their method to reduce or eliminate fat tissue using a controlled release formulation using techniques well known in the art and demonstrate this method actually successfully reduces or eliminates fat tissue, Silvestri et al. teach a type of controlled release formulation with improved properties that could be used in a method similar to that of Goldenberg et al. and that the controlled release formulation could have two active substances and

Merwin et al. teach a specific compound that would prevent angiogenesis and demonstrate it works on epithelial cells derived from fat tissue.

33. Therefore, the invention of claims 1-3, 5, 6, 9-12, 14, 17 and 24-26 would have been obvious, as a whole, at the time the instant invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Tracy Vivlemore
Examiner
Art Unit 1635

TV
July 29, 2004

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER